

DHSR Adult Care Licensure Section

Fiscal Impact Analysis

Permanent Rule Amendment without Substantial Economic Impact

Agency: North Carolina Medical Care Commission

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Impact: State government impact: No  
Local government: No  
Federal government Impact: No  
Substantial economic impact: No

Authorizing Statutes: G.S. 131D-2.16; 131D-4.5; 143B-165

Introductory Note:

The rules have been amended to allow adult care homes (adult care homes of more than six beds and family care homes) to package medications needed for a resident in a leave of absence from the facility instead of only being able to send one dose of each medication with the resident, sending all of the medication with the resident, or having a dispensing practitioner package the amount of medications needed for the leave of absence. It is not unusual for some adult care home residents to take a leave of absence for several days during which time they need to continue their medication regimen. It can be difficult for facilities to get specific amounts of medications for a resident's leave repackaged by a pharmacy due to distance and time factors. Some pharmacies will not repackage. The other alternative has been to send all the resident's medications with the resident or responsible party, but this creates resident health and safety concerns since the facility is no longer accountable for the medications as well as their administration. The amended rule will make the process of sending the needed medications with the resident easier yet assuring accountability for the medications and promoting safety of the resident.

Summary of Changes:

10A NCAC 13F .1003 and 13G .1003 – amendment allows for transfer of medication(s) from one container to another by the facility in cases of a resident temporarily leaving the facility as opposed to only a dispensing practitioner being able to repackage or all the medications in original packaging having to be sent with resident.

10A NCAC 13F .1010 and 13G .1010 – amendment addresses how the medication(s) to be sent with the resident on leave is to be packaged and labeled, who can do the packaging and labeling, how the resident is to be informed about the medication and what documentation the facility must have.

Anticipated Fiscal Impact:

There would be no fiscal impact on federal, state and local governments.

The impact on private sector entities, namely adult care and family care home providers, would be minimal but cannot be quantified due to lack of data on numbers of residents leaving facilities temporarily and number of medications involved. There could be some cost savings to those facilities who have been getting pharmacies to repackage medications if they do not pass this cost along to the residents. Cost to facilities would be in the packaging they choose to use for medications to be released with the resident. The rules do not address what the packaging has to be, only that it has to properly labeled.

## APPENDIX

10A NCAC 13F .1003 is amended with changes as published in 29:08 NCR, pp. 907-909 as follows:

### 10A NCAC 13F .1003 MEDICATION LABELS

(a) Prescription legend medications dispensed by the pharmacy shall have a legible ~~{printed}~~ label with the following information:

- (1) the name of the resident for whom the medication is prescribed;
- (2) the most recent date of issuance;
- (3) the name of the prescriber;
- (4) the name and concentration of the medication, quantity dispensed, and prescription serial number;
- (5) directions for use stated and not abbreviated;
- (6) a statement of generic equivalency shall be indicated if a brand other than the brand prescribed is dispensed;
- (7) the expiration date, unless dispensed in a single unit or unit dose package that already has an expiration date;
- (8) auxiliary statements as required of the medication;
- (9) the name, address and telephone number of the dispensing pharmacy; and
- (10) the name or initials of the dispensing pharmacist.

(b) For medication systems ~~such as med-paks and multi-paks when in which~~ two or more prescribed solid oral dosage forms are packaged and dispensed together, labeling shall be in accordance with Paragraph (a) of this Rule and the label or package shall also have a physical description or identification of each medication contained in the package.

(c) The facility shall assure the container is relabeled by a licensed pharmacist or a dispensing practitioner at the refilling of the medication when there is a change in the directions by the prescriber. The facility shall have a procedure for identifying direction changes until the container is correctly labeled. No person other than a licensed pharmacist or dispensing practitioner shall alter a prescription label.

(d) Non-prescription medications shall have the manufacturer's label with the expiration date visible, unless the container has been labeled by a licensed pharmacist or a dispensing ~~practitioner.~~ practitioner in accordance with Paragraph (a) of this Rule. Non-prescription medications in the original manufacturer's container shall be labeled with at least the resident's name and the name shall not obstruct any of the information on the container. Facility staff may label or write the resident's name on the container.

(e) Medications, prescription and non-prescription, shall not be transferred from one container to another except when prepared for a resident's leave of absence or administration to a resident.

~~(f) Prescription medications leaving the facility shall be in a form packaged and labeled by a licensed pharmacist or a dispensing practitioner. Non-prescription medications that are not packaged or labeled by a licensed pharmacist or dispensing practitioner must be released in the original container and directions for administration must be provided to the resident or responsible party. The facility shall assure documentation of medications, including quantity released and returned to the facility.~~

*History Note:* Authority G.S. ~~131D-2~~ 131D-2.16; 131D-4.5; 143B-165;  
Eff. July 1, ~~2005~~. 2005;  
Amended Eff. April 1, 2015.

10A NCAC 13G .1010 is amended with changes as published in 29:08 NCR, pp. 907-909 as follows:

#### **10A NCAC 13G .1010 PHARMACEUTICAL SERVICES**

(a) A family care home shall allow the residents the right to choose a pharmacy provider as long as the pharmacy ~~will~~ provides services that are in compliance with the facility's medication management policies and procedures.

(b) There shall be a current, written agreement with a licensed pharmacist or a prescribing practitioner for pharmaceutical care services according to Rule .1009 of this Section. The written agreement shall include a statement of the responsibility of each party.

(c) The facility shall assure the provision of pharmaceutical services to meet the needs of the residents including procedures that assure the accurate ordering, receiving and administering of all medications prescribed on a routine, emergency, or as needed basis.

(d) The facility shall assure the provision of medication for residents on temporary leave from the facility or involved in day activities out of the facility. ~~{Medications prepared for a resident's temporary leave of absence shall be packaged in a manner that facilitates safe administration and enables the resident or resident's responsible person to identify the correct medication and correct administration time for each medication. The amount of medications necessary to cover the duration of the resident's absence may be taken from the supply of medication already dispensed to the resident and prepared by a medication aide, or licensed health professional with authority to administer or dispense medications. The following information for each medication prepared for the resident's absence shall be provided verbally and in writing to the resident or the person who is designated as the resident's responsible person during the absence:~~

~~(1) — the name and strength of the drug;~~

~~(2) — the directions for administration as prescribed by the resident's physician; and~~

~~(3) — any cautionary information from the original prescription package.~~

~~For medications removed from the resident's supply of medications, the name of the resident and the information provided in Subparagraphs (1) and (2) shall be provided directly on the container containing the medication. The facility shall maintain documentation of medications provided for the resident's leave of absence, including the quantity released from the facility, the quantity returned to the facility, and the name of the individual who prepared the medication for the resident's leave of absence.}~~

The facility shall have written policies and procedures for a resident's temporary leave of absence. The policies and procedures shall facilitate safe administration by assuring that upon receipt of the medication for a leave of absence the resident or resident's responsible person is able to identify the medication, dosage, and administration time for each medication provided for the temporary leave of absence. The policies and procedures shall include at least the following provisions:

(1) The amount of resident's medications provided shall be sufficient and necessary to cover the duration of the resident's absence. For the purposes of this Rule, sufficient and necessary means the provision of the amount of medication to be administered during the leave of absence or the

provision of only a current dose pack, card, or container if the current dose pack, card, or container has enough medication for the planned absence;

(2) Written and verbal instructions for each medication to be released for the resident's absence shall be provided to the resident or the person who is designated as the resident's responsible person during the absence and shall include at least:

(A) the name and strength of the medication;

(B) the directions for administration as prescribed by the resident's physician;

(C) any cautionary information from the original prescription package if the information is not on the container released for the leave of absence; and

(3) Labeling of the resident's medication container for the leave of absence shall be legible and include at least the name of the resident and the name and strength of the medication.

The facility shall maintain documentation of medications provided for the resident's leave of absence, including the quantity released from the facility and the quantity returned to the facility. The documentation of the quantities of medications released from and returned to the facility for a resident's leave of absence shall be verified by signature of the facility staff and resident or resident's responsible person upon the medications' release from and return to the facility.

(e) The facility shall assure that accurate records of the receipt, use and disposition of medications are maintained in the facility and readily available for review.

*History Note: Authority G.S. ~~131D-2~~ 131D-2.16; 131D-4.5; 143B-165;  
Eff. July 1, ~~2005~~ 2005;  
Amended Eff. April 1, 2015.*

10A NCAC 13G .1003 is amended with changes as published in 29:08 NCR, pp. 907-909 as follows:

**10A NCAC 13G .1003 MEDICATION LABELS**

(a) Prescription legend medications as dispensed by the pharmacy shall have a legible ~~{printed}~~ label with the following information:

- (1) the name of the resident for whom the medication is prescribed;
- (2) the most recent date of issuance;
- (3) the name of the prescriber;
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- (6) a statement of generic equivalency shall be indicated if a brand other than the brand prescribed is dispensed;
- (7) the expiration date, unless dispensed in a single unit or unit dose package that already has an expiration date;
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(b) For medication systems ~~such as med-paks and multi-paks when in which~~ two or more prescribed solid oral dosage forms are packaged and dispensed together, labeling shall be in accordance with Paragraph (a) of this Rule and the label or package shall also have a physical description or identification of each medication contained in the package.

(c) The facility shall assure the container is relabeled by a licensed pharmacist or a dispensing practitioner at the refilling of the medication when there is a change in the directions by the prescriber. The facility shall have a procedure for identifying direction changes until the container is correctly labeled. No person other than a licensed pharmacist or dispensing practitioner shall alter a prescription label.

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(e) Medications, prescription and non-prescription, shall not be transferred from one container to another except when prepared for a resident's leave of absence or administration to a resident.

~~(f) Prescription medications leaving the facility shall be in a form packaged and labeled by a licensed pharmacist or a dispensing practitioner. Non-prescription medications that are not packaged or labeled by a licensed pharmacist or dispensing practitioner must be released in the original container and directions for administration must be provided to the resident or responsible party. The facility shall assure documentation of medications, including quantity released and returned to the facility.~~

~~Note: Dispensing of medications is restricted to pharmacists or other health care practitioners that are approved by the North Carolina Board of Pharmacy. Repackaging or providing more than one dose of a prescription medication, including unit dose prescription medications, for subsequent administration is an act of dispensing.~~

*History Note: Authority G.S. ~~131D-2~~ 131D-2.16; 131D-4.5; 143B-165; ~~S.L. 1999-0334~~  
Temporary Adoption Eff. December 1, 1999;  
Eff. July 1, ~~2000~~ 2000;  
Amended Eff. April 1, 2015.*



10A NCAC 13G .1010 is amended with changes as published in 29:08 NCR, pp. 907-909 as follows:

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(b) There shall be a current, written agreement with a licensed pharmacist or a prescribing practitioner for pharmaceutical care services according to Rule .1009 of this Section. The written agreement shall include a statement of the responsibility of each party.

(c) The facility shall assure the provision of pharmaceutical services to meet the needs of the residents including procedures that assure the accurate ordering, receiving and administering of all medications prescribed on a routine, emergency, or as needed basis.

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~~(4) — the name and strength of the drug;~~

~~(5) — the directions for administration as prescribed by the resident's physician; and~~

~~(6) — any cautionary information from the original prescription package.~~

~~For medications removed from the resident's supply of medications, the name of the resident and the information provided in Subparagraphs (1) and (2) shall be provided directly on the container containing the medication. The facility shall maintain documentation of medications provided for the resident's leave of absence, including the quantity released from the facility, the quantity returned to the facility, and the name of the individual who prepared the medication for the resident's leave of absence.}~~

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(4) The amount of resident's medications provided shall be sufficient and necessary to cover the duration of the resident's absence. For the purposes of this Rule, sufficient and necessary means the provision of the amount of medication to be administered during the leave of absence or the

provision of only a current dose pack, card, or container if the current dose pack, card, or container has enough medication for the planned absence;

- (5) Written and verbal instructions for each medication to be released for the resident's absence shall be provided to the resident or the person who is designated as the resident's responsible person during the absence and shall include at least:

(D) the name and strength of the medication;

(E) the directions for administration as prescribed by the resident's physician;

(F) any cautionary information from the original prescription package if the information is not on the container released for the leave of absence; and

- (6) Labeling of the resident's medication container for the leave of absence shall be legible and include at least the name of the resident and the name and strength of the medication.

The facility shall maintain documentation of medications provided for the resident's leave of absence, including the quantity released from the facility and the quantity returned to the facility. The documentation of the quantities of medications released from and returned to the facility for a resident's leave of absence shall be verified by signature of the facility staff and resident or resident's responsible person upon the medications' release from and return to the facility.

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